Filed: September 8, 2003

Response to Restriction Requirement

U.S. App. No. 10/658,619 Inventors: Gambale et al.

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Amendments to the Specification:

Please replace the paragraph at page 9, from line 5 through line 17, with the following paragraph:

The wire 11 is then withdrawn proximally, followed by proximal withdrawal of the cable 10, to withdraw the needle 8 from the tissue portion 19a. The suction is then discontinued allowing the U-shaped tissue portion 19a to be released from the cavity 7. As shown in FIG. 3, the released tissue is left with a suture thread 14 passing through the two layers of tissue that form the U-shaped fold 19a. One end of the suture is joined to the tag 12 that remains captured in the chamber 20 and the other end of the suture extends through the patient's esophagus and out of the mouth. Finally, the endoscope and sewing dewing device are withdrawn from the patient. In so doing, the thread 14 is pulled partially through the tissue portion 19a, as the captured tag 12 is withdrawn proximally and brought outside the patient. With both ends of the thread 14 outside of the patient, the thread can be knotted and the knot endoscopically pushed down to the suture site and severed by an endoscopic knot pusher such as that disclosed in U.S. Pat. No. 6,010,515 (Swain et al).

Please replace the paragraph running from page 22, line 14 through page 23, line 5, with the following paragraph:

FIGS. 19A-19C show additional tissue capture device embodiments 410, 418 and 424 that are implantable directly into captured tissue mounds and have barbs 412 to prevent the device from becoming withdrawn from the captured tissue portions after implantation. In FIG. 19A the device 410 is provided with multiple barbs 412 spaced along each prong 414 provided for insertion into each captured tissue mound 306. In FIG. 19B a single barb 412 is provided on each prong 420. In FIG. 19C the tissue capture device 424 is provided with a single barb 412 on each prong 422 as with the embodiment described above in connection with FIG. 19B. However, the device 424

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further includes a tab 426 serving as a junction for the ends of each prong 412. The tab 426 provides a convenient means for varying the number of prongs 412 that can extend from a given device. In other words, two two, three or more tissue mounds could be captured with a single device by providing the necessary number of prongs and joining them together at the tab 426. Additionally, the tab is beneficial in stabilizing the device during implantation. It is noted that each of the embodiments shown in FIGS. 19A-19C may be formed from flexible stainless steel that is resiliently bendable. The devices maintain their shape (generally U-shaped) but may be deflected as required during insertion into the tissue mounds 306. It is noted that the barbs 412 may be deflected to a low profile configuration during insertion into the tissue, but if provided with an arrow shape, they will become anchored within the tissue upon application of a withdrawal force on the device.

Please replace the paragraph at page 9, from line 5 through line 17, with the following paragraph:

FIG. 22 shows another embodiment of a tissue capture device delivered into precaptured tissue mounds that does not require a shape change after delivery to attain the tissue mounds in close proximity to each other. The device 450 comprises a helical coil spring that is wound in two opposing helical directions. A proximal portion of the spring 452 52 is wound in a first helical direction while the distal portion 454 of the spring is wound in the opposite helical direction so that once implanted in the tissue, each end of the spring will restrain the other end from unwinding out of the tissue. The spring is preferably wound from a flat metal ribbon to provide a greater contact area with the tissue. The ribbon may be canted so that the cross section of each coil 456 presents an angle that is acute to the longitudinal axis of the spring coil 450. To deliver delivery the device, the tissue apposition device as shown in FIG. 6 may be used to pre-capture the multiple tissue mounds 306. The device 450 may be delivered longitudinally through the tissue mounds in a hypotube or hypodermic needle then pushed out of the tubing while

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placed within the tissue to avoid interference of the reverse wound coils of the device with the tissue during insertion.

Please replace the paragraph running from page 25, line 9 through page 26, line 22, with the following paragraph:

A device for delivering multiple darts to a plurality of tissue areas is shown in FIGS. 24A-24G. The dart delivery device 472 may be similar to the prior art band ligator device shown in FIGS. 7A-7C. The delivery device 472 is configured to be mounted at the distal end of an endoscope 118 as shown in FIG. 24A and comprises a slender pole suction chamber 474 with a supple distal tip 476 for engaging tissue areas and for creating a relatively vacuum tight seal such that when suction is applied to the chamber 474, a tissue mound 306 is drawn into the chamber. The suction chamber also supports along the center of its longitudinal axis a rotatable auger spring 478 for driving the darts distally into the captured tissue mound 306. The spring 478 rotates under motion from torque cable 480 that extends through the working channel of the endoscope 118 and joins the spring in the suction chamber 474. Multiple darts 460 reside between the coils 482 of the spring such that coils fit closely against the stem portion 464 of the dart and abut the enlarged penetrating tip 462 and tether receptacle 468. In this engagement, when the spring rotates, the darts 460 will be advanced as a ride between the individual coils 478. As shown in FIG. 24B, continued rotation of the auger spring 478 serves to drive the first distal dart 460 into the captured tissue mound 306. The darts are pre-loaded with a tether 470 that is not yet tightened so that the darts can be aligned longitudinally in the auger spring for sequential delivery. FIG. 24C shows a dart fully seeded into a tissue mound 306 such that the penetrating tip 462 and stem 464 are embedded in the tissue mound and the tether receptacle 468. After implantation of the first dart, the vacuum is released and the delivery device 472 moved to a new tissue location. As shown in FIG. 24D, a new tissue mound is aspirated into the suction chamber 474 and as shown in FIG. 24E, the auger spring 478 is rotated to advance the second dart 460 into the second tissue

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mound 306. Tether 470 remains joined to both the first and second darts 460 throughout the delivery process. After delivery of the second dart, the vacuum may be released, leaving the implanted darts 460 in tissue that has returned to its natural configuration. Tether key 482, which has also been advanced in line behind the darts by the <u>rotation</u> rogation of the auger spring 478, receives the free end of the tether 470. After delivery of the second dart 460, the auger spring 478 is rotated and reversed to draw the tether key 482 proximally in order to tighten the tether 470 between the two implanted darts 460 as is shown in FIG. 24F. The tether hole 466 of the tether receptacle 468 of each dart may be configured to receive the tether 470 in a ratcheted fashion such that the tether passes freely in one direction (i.e., the direction of tightening) but is locked and prevented from sliding in the opposite direction (i.e., the direction that loosens the tether between the two darts). Such a ratcheting configuration may be similar to that of the locking disc described in the embodiments of FIG. 21. As shown in FIG. 25, after the tether 470 has been pulled to draw the two implanted darts 460 together, the tissue into which they are implanted again form defined mounds 306 with perhaps some additional folds 484 present between the captured mounds. After the tether has been tightened sufficiently, the tether key 482 can be triggered to release the free end of the tether so that the delivery device 472 can be removed from the tissue location.

Please replace the paragraph running from page 26, line 23 through page 27, line 10, with the following paragraph:

FIG. 26A shows an embodiment of the invention employing a tissue apposition device configured as a band ligator such as that shown in FIG. 7A-7C discussed above. The <u>band bank</u> ligator is advanced to adjacent tissue portions, tissue mound 306 aspirated in bands 134 released on the tissue mounds and endoscopic band ligator instrument removed, shown in FIG. 26B, next, a separate tissue capture delivery device 474 is advanced to the adjacent tissue mounds 306, now defined by ligating bands 134, temporarily placed around them. A tissue capture device 476 comprising a length of

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filament material and having arrow shaped barbs at each end is then advanced from the delivery device 474 directly into one of the tissue mounds 306 with continued advancement by pusher 478 so that at least one of the barbs 480 from the tissue capture device reaches the adjacent tissue mound 306 as shown in FIG. 26C. With each tissue mound 306 receiving an opposite facing barb 480, the mounds will be held in close proximity. After delivery of the tissue capture device 476, the bands either may be cut away from the tissue portions or may be made of a dissolvable material so that the tissue mounds 306 are left with only the capture device 476 placed to hold them together as shown in FIG. 26D.